Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12897 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0456]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction, Reporting and Recordkeeping Requirements,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 1997 (62 FR 62773), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0140. The approval expires on April 30, 2001.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12902 Filed 5–14–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0287]

Guidance for Industry on Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This is revision 1 of the guidance. The guidance has been revised to reflect the recent availability of buspirone hydrochloride tablets in 15-milligram dosage forms. Bioequivalence is tested using the highest available dosage of the reference listed drug. The revised guidance also notes the nonlinearity of buspirone at multiple-dosing.

DATES: Written comments on agency guidance documents may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sikta Pradhan, Center for Drug Evaluation and Research (HFD–652), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION: This guidance document is a level 2 guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on buspirone hydrochloride tablets in vivo bioequivalence and in vitro dissolution testing. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the guidance at any time to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12903 Filed 5–14–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0276]

Guidance for Industry on Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements.'' As required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act), this guidance for industry describes the standards for the prompt review of efficacy supplements. It also is intended to define those efficacy supplements that are eligible for priority review.

DATES: Written comments may be submitted on the guidance document by August 13, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration,